April 4, 2006

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852
Attn: Laurie Burke

Re: Guidance for Industry Patient-Reported Outcome Measures: Use in Medical Product Development to Support Labeling Claims [Docket No. 2006D-0044]

Dear Ms. Burke,

Boston Scientific Corporation is a worldwide developer, manufacturer and marketer of minimally-invasive medical devices. Our products are used in a wide range of clinical disciplines including Interventional Electrophysiology, Endoscopy, Gastroenterology, Gynecology, Interventional Cardiology, Neuromodulation, Neurovascular, Oncology, Peripheral Interventions, Urology and Vascular Surgery.

Boston Scientific welcomes the opportunity to comment on the Food and Drug Administration's (FDA's) draft Guidance for Industry: Patient-Reported Outcome Measures: Use in Medical Product Development to Support Labeling Claims [Docket No. 2006D-0044]. We commend the effort the Agency has put forth to develop the draft guidance document.

We appreciate FDA's recognition of the value of patient reported outcomes (PROs) in evaluating medical therapies or interventions and developing a guidance document on how these data can support labeling claims. In places within the guidance, FDA acknowledges that certain therapies and treatments have unique characteristics that require unique trial methodology to adequately and appropriately assess clinical value. However, FDA does not apply this perspective consistently throughout the document. We recommend the Agency be consistent in accepting alternative methodologies that will allow for the collection of valuable PRO data that can be used to support labeling claims.

Evaluating PRO Instruments

The FDA recognizes that there are multiple modes of data administration. The document states, "the FDA intends to review the comparability of data obtained when using multiple modes of administration to determine whether pooling of results from the multiple modes is appropriate." We would assert that as long as the instrument is validated in each mode, it is appropriate and acceptable to combine the results.

Modification of an Existing Document

The FDA recognizes that when a PRO instrument is modified, additional validation studies may be needed to confirm measurement properties. The guidance states, "for example, if the PRO instrument is to be used in an entirely new population of patients, a

small randomized study to ascertain the measurement properties in the new population may minimize the risk that the instrument will not perform adequately…." We appreciate the Agency's concern that by modifying an instrument, its ability to measure relevant concepts and predict future outcomes may be compromised. However, it may also be necessary and methodologically appropriate to also consider non-randomized validation studies for select therapies. The literature supports the feasibility and acceptability of validating a modified or completely new instrument within the context of a single arm studies.

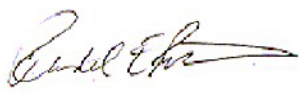
Study Design

With respect to study design, it is important to note that there are methodological and ethical challenges associated with conducting randomized controlled trials for certain treatments. For example, patients may be reluctant to participate in a trial where they may be randomized to a drug versus a more invasive treatment or a device versus no device. In some cases, randomization may also be inappropriate when risks are high or benefits are not clinically disputed. We appreciate the Agency's acknowledgement of these unique considerations. Specifically, the guidance notes that "there are certain situations, particularly in the development of medical devices, where blinding is not feasible and other situations where there is no reasonable control group (and therefore no randomization)." In such cases, single arm studies may be more practical to implement.

The Agency also highlights the importance of maintaining data integrity. Specifically, the guidance states, "Sponsors should plan to avoid the following: Access to unblinded data." We agree that maintaining data integrity is critical. However, as previously acknowledged by the FDA within the guidance, there are certain situations where blinding may not be feasible. In such cases, alternative study designs are often used. For example, single arm studies, observational studies, multi-center studies, and registries can effectively and accurately measure efficacy without compromising data integrity.

In closing, we appreciate the opportunity to comment on the proposed PRO guidance document. We applaud the Agency's acknowledgment that certain therapies have unique trial considerations and would recommend the consistent application of these considerations throughout the entire guidance.

Sincerely,



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